

GOOD REGULATORY PRACTICE: THE ROLE OF STRONG CENTRAL GOVERNMENT COORDINATION IN TBT AGREEMENT IMPLEMENTATION

Communication from the United States

The following communication, dated 9 June 2009, is being circulated at the request of the delegation of the United States.

I. INTRODUCTION

1. In its 28 October 2008 submission to the WTO Committee on Technical Barriers to Trade, New Zealand outlined its experience with its new model for domestic regulatory cooperation, the Regulators' Forum, which aims to promote better alignment and coordination across regulators, policy makers, and infrastructure bodies with a view to achieving good regulatory practice.¹ The experiences of New Zealand and the United States² demonstrate that there is no "one size fits all" approach to creating greater coordination among regulators. The United States found the description of New Zealand's approach to be very useful and agrees that "continual sharing of information on different models of regulatory cooperation can benefit all Members of the Committee."

2. The United States notes that, in the Fourth Triennial Review, the Committee emphasized "the benefits of simplifying and improving regulatory environments and emphasizes the need for openness, transparency, and accountability in the development and application of technical regulations and conformity assessment procedures".³ The Committee also recognized "the usefulness of a Member establishing administrative mechanisms for coordination between competent authorities," noted that "a number of Members have set up TBT coordinating committees to facilitate communication and cooperation between relevant government authorities," and stressed "the importance of including local governments as well as non-governmental parties in the domestic consultation activities."⁴ Consequently, the Committee agreed to share experiences on, *inter alia*, "how good regulatory practices have been integrated into Members' regulatory structures, including the use of mechanisms to ensure openness, transparency and accountability of the regulatory processes" and "the establishment of domestic administrative mechanisms to facilitate cooperation and coordination between competent authorities and coordination with other stakeholders".⁵

¹ Committee on Technical Barriers to Trade, "The Regulators' Forum: A New Zealand Example of Domestic Regulatory Coordination," G/TBT/W/294, 28 October 2009.

² The United States has previously submitted two GRP experience papers: G/TBT/W/220, 30 June 2003 and G/TBT/W/258, 26 October 2005, as well as a paper on "Determining the Need to Regulate," G/TBT/W/285, 19 March 2008.

³ Fourth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade Under Article 15.4, G/TBT/19, 14 November 2006, para. 8.

⁴ Id. at para. 17.

⁵ Id. at para. 19(d) and (e).

3. This submission provides additional background on the importance of regulatory coordination and cooperation in ensuring good regulatory practice and adherence to TBT obligations, and provides an overview of how the United States attempts to accomplish these objectives through strong central government management of its regulatory regime, an effective interagency trade policy mechanism, and robust public consultation.

II. BACKGROUND

4. Regulatory coordination and consistency are indispensable for ensuring good regulatory practice and for preventing the creation of unnecessary obstacles to trade. The TBT Committee has emphasized the importance of effective coordination among trade officials, standards organizations, and regulators by Members in implementing the TBT Agreement.⁶

5. Meanwhile, APEC and OECD reviews and studies of countries' regulatory reform efforts have demonstrated that a well coordinated and "well organized and monitored [regulatory] process, driven by 'engines of reform' with clear accountability for results, is important for the success of a country's regulatory quality policy".⁷ The APEC-OECD Integrated Checklist on Regulatory Reform integrates APEC and OECD principles on regulatory reform, including the importance of accountability and coordination within governments.⁸

6. In addition, in its model procedures and guidance notes for implementation of the WTO TBT Agreement, the International Trade Centre has stressed the importance of the establishment of strong coordinating bodies by central governments in order to facilitate implementation of good regulatory practice and implementation of their TBT obligations through review of regulations, regulatory impact analysis, and interagency cooperation.⁹

III. IMPLEMENTATION OF GOOD REGULATORY PRACTICE PRINCIPLES IN THE UNITED STATES: STRONG CENTRAL GOVERNMENT MANAGEMENT AND COORDINATION

7. Effective coordination of regulatory programmes and activities often depends upon strong central government management of the regulatory regime. For example, in the United States, centralized regulatory oversight in the Office of Management and Budget (OMB) in the executive branch of the government is intended in part to minimize duplication and inconsistency among

⁶ Committee on Technical Barriers to Trade, Workshop on Good Regulatory Practice, G/TBT/GEN/67/Rev.1, 17 March 2008, paras. 2 and 4; Second Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade, G/TBT/9, 13 November 2000, para. 7; and David Shortall, "Regulatory Reform and Market Openness: Processes to Assess Effectively The Trade and Investment Impact of Regulation," OECD Trade Policy Working Paper No. 28, pp. 31-32.

⁷ Pedro Andres Amo and Delia Rodrigo, Background Document: *Oversight Bodies for Regulatory Reform*, OECD, February 2007, pp. 1-9; APEC and OECD, *Synthesis Report: The APEC – OECD Integrated Checklist for Regulatory Reform: Results of Self Assessments, 2006-2007, in Five Economies*, First Economic Committee Meeting, Lima, Peru, 25-26 February 2008; OECD, *Regulatory Performance: Ex Post Evaluation of Regulatory Policies*, Paris: OECD, 22 September 2003, <http://www.oecd.org/dataoecd/34/30/30401951.pdf>; OECD Background Document on Oversight Bodies for Regulatory Reform, Paris: OECD, 2007, <http://www.oecd.org/dataoecd/4/41/36785272.pdf>; APEC-OECD Integrated Checklist on Regulatory Reform: *Self-Assessment by the Commonwealth of Australia*, APEC Economic Committee Meeting, Cairns, Australia, June 28-29, 2007; and OECD, *Regulatory Impact Analysis in OECD countries, Challenges for Developing Countries*, Paris, 2005.

⁸ See <http://www.oecd.org/dataoecd/41/9/34989455.pdf>.

⁹ International Trade Centre (ITC), *Manual of Model Procedures and Guidance Notes for the Implementation of the WTO Agreement on Technical Barriers to Trade*, Bulletin No. 82, April 2007, para. 8.3 (p. 12) and Annexes 4, 4A, and 4B (pp. 41-45).

regulations and to balance the demands of potentially competing or conflicting regulatory agencies and programmes.¹⁰

8. Coordination between regulatory programmes was an early objective of regulatory reform in the United States and continues to be an important motivating force, under both major political parties, for stronger central management.¹¹ The first major presidential initiative to improve regulatory management was developed in 1971 to improve interagency coordination of regulation. Interagency consultation and coordination were further strengthened in 1978, and executive orders issued in 1981 and 1993 further refined and consolidated regulatory oversight within OMB to minimize regulatory inconsistency, conflict, and duplication.¹²

9. Presently, U.S. regulatory policy is governed by presidential Executive Order (E.O.) 12866¹³ which sets out principles of regulation and requires coordinated review of Federal¹⁴ agency rulemaking "to ensure that regulations are consistent with applicable law, the President's priorities, and....that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency."¹⁵ The Order also requires agencies, when feasible, to consult with State and local governments before issuing regulations that may impact those governmental entities and to assess the impact of Federal regulations on State and local governments and, as appropriate, seek to harmonize Federal regulations with related State and local governmental functions.¹⁶ Further, E.O. 12866 provides that agencies, in determining whether and how to regulate, should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating and to make the regulatory process more accessible and open to the public. E.O. 12866 thus reinforces the philosophy that agencies should select the regulatory approach that maximizes net benefits to society, unless otherwise constrained by law.

10. Within OMB, the Office of Information and Regulatory Affairs (OIRA) is the repository of expertise concerning regulatory issues, methodologies, and procedures that affect more than one Federal agency and, as such, oversees regulatory decision-making in U.S. agencies.¹⁷ Pursuant to E.O. 12866, OIRA oversees the regulatory process for the Executive Branch by coordinating interagency review of draft regulations and regulatory impact analyses of agencies to ensure that they are consistent with the Order's regulatory principles and with the President's policies and priorities and to ensure that regulations of one agency do not conflict with those of another. As the office that reviews significant regulations of the Federal government, OMB is in the best position to ensure that the regulatory process flows smoothly, just as it is with its other central review functions with respect to the fiscal budget, legislative proposals, and programme management.

¹⁰ APEC and OECD, "Synthesis Report: The APEC – OECD Integrated Checklist for Regulatory Reform: Results of Self Assessments, 2006-2007, in Five Economies," First Economic Committee Meeting, Lima, Peru, February 25-26, 2008, para. 7; and "Regulatory Reform in the United States: Enhancing Market Openness Through Regulatory Reform." Paris: OECD, 1999, p. 1.

¹¹ OECD, *Regulatory Reform in the United States: Government Capacity to Ensure High Quality Regulation*, 1999, pp. 14-20.

¹² Ibid; Presidential Executive Order (E.O.) 12291, February 17, 1981; and E.O. 12866, September 30, 1993.

¹³ E.O. 12866 (<http://www.whitehouse.gov/omb/inforeg/eo12866.pdf>).

¹⁴ As used in this paper, the term "Federal" refers to the central level of government in the United States.

¹⁵ See E.O. 12866.

¹⁶ Ibid. The U.S. Enquiry Point notifies both Federal and State-level proposed technical regulations and conformity assessment procedures, pursuant to Articles 2, 3, 5, and 7 of the TBT Agreement. From 2007-2009, the United States notified approximately 120 proposed State-level measures to the WTO.

¹⁷ Ibid.

11. To ensure adequate consideration of specific regulatory impacts—such as those on small businesses, competition, and market openness—OIRA’s interagency review process involves extensive consultation with other U.S. agencies with expertise in these areas. For example, if questions arise with respect to the WTO-consistency of proposed or final regulations, OIRA includes the United States Trade Representative (USTR) in the Federal interagency review process that precedes publication of the regulations in the U.S. *Federal Register*.¹⁸ In such instances, OMB, USTR, and the issuing regulatory agency seek to ensure that proposed regulatory measures comply with U.S. obligations under the WTO and other trade agreements, and are not otherwise unnecessarily trade restrictive. In this regard, the Trade Agreements Act of 1979, as amended, requires U.S. Federal agencies to ensure that their standards-related activities conform to specific TBT Agreement obligations, for example, that technical regulations do not create unnecessary obstacles to trade or treat imported products less favorably than like domestic products.

12. In addition, OMB has long provided guidance on regulatory analysis and the assessment of costs and benefits. The latest such guidance is OMB’s Circular A-4, Regulatory Analysis, which OMB released in September 2003.¹⁹ OMB developed the guidelines in collaboration with the President’s Council of Economic Advisors, and revised the proposed guidelines based on public comments, peer review, and interagency review. Circular A-4 states that “[c]oncerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully.”

13. The successful implementation of a regulatory reform programme depends upon strong and committed political leadership. In the United States, the support of the President has been critical to its success. Early in his Administration, President Obama expressed his support for centralized review of Federal regulations by OMB, affirming it as both a legitimate and appropriate means of coordinating regulatory policy.²⁰ Because the President believes that a great deal has been learned about how to improve the process of regulatory review since the fundamental principles and structures governing regulatory review were set out in E.O. 12866, he has directed the Director of OMB to consult with representatives of regulatory agencies to produce a set of recommendations for a new Executive Order on Federal regulatory review.²¹

IV. INTERAGENCY TRADE POLICY COORDINATION

14. The Office of the United States Trade Representative (USTR), meanwhile, oversees an interagency trade policy process that incorporates input from dozens of government agencies, including regulatory agencies, in the implementation and coordination of U.S. trade policy. Three tiers of committees develop U.S. Government positions on international trade and trade-related investment issues.²² The first tier is the Cabinet-level National Economic Council (NEC), which is chaired by the President. NEC representation includes the Vice President, the Secretaries of State, Treasury, Agriculture, Commerce, Labor, Housing and Urban Development, Transportation, and Energy, the Administrator of the Environmental Protection Agency (EPA), the Chair of the Council of Economic Advisers (CEA), the Director of OMB, the USTR, the National Security Advisor, and the Assistants to the President for Economic Policy, Domestic Policy, and Science and Technology

¹⁸ OECD, “Regulatory Reform in the United States: Government Capacity to Ensure High Quality Regulation,” 1999, pp. 17-18.

¹⁹ <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>.

²⁰ 74 Fed Reg 5977 (3 February 2009).

²¹ President Obama emphasizes, among other things, that the recommendations should offer suggestions for the relationship between OIRA and Federal agencies; provide guidance on disclosure and transparency; encourage public participation in agency regulatory processes; identify means for ensuring that regulatory review does not produce unnecessary delay; clarify the role of the behavioral sciences in formulating regulatory policy; and identify the best tools for achieving public goals through the regulatory process. Ibid.

²² USTR, *2009 Trade Policy Agenda and 2008 Annual Report of the President of the United States*, 27 March 2009, pp. 242-243.

Policy. All executive departments and agencies, whether or not represented on the NEC, coordinate economic policy through the NEC.

15. The Trade Policy Review Group (TPRG) and the Trade Policy Staff Committee (TPSC), administered and chaired by USTR, are the sub-cabinet interagency trade policy coordination groups central to this process. The TPRG is composed of high level political appointees (Under Secretaries and Assistant Secretaries) from twenty government agencies. The TPSC is staffed by senior civil servants. Supporting the TPSC are more than 60 subcommittees responsible for specialized areas and several task forces charged with particular issues. In particular, there is a TPSC subcommittee on technical barriers to trade that addresses trade issues regarding technical regulations, standards, and conformity assessment procedures.

16. The TPRG and the TPSC are comprised of the Departments of Commerce, Agriculture, State, Treasury (which houses the Alcohol and Tobacco Tax and Trade Bureau (TTB)), Labor (which houses the Occupational Health and Safety Administration (OSHA)), Justice, Defense, Interior, Transportation, Energy, Homeland Security, and Health and Human Services (which houses the Food and Drug Administration (FDA)), EPA, OMB, CEA, the Council on Environmental Quality (CEQ), the Agency for International Development (AID), NEC, and the National Security Council.²³ The U.S. International Trade Commission (ITC) is a non-voting member of the TPSC and an observer at TPRG meetings. Representatives of other agencies, such as the Consumer Product Safety Commission (CPSC), may be invited to attend meetings depending on the specific issues discussed. The National Institute of Standards and Technology (NIST), which is part of the Department of Commerce and houses the U.S. WTO TBT Inquiry Point, also frequently attends meetings to provide technical expertise on standards and conformity assessment issues, as well as updates on Inquiry Point activities.

17. On TBT matters, the vast majority of decision-making takes place at the TPSC subcommittee on technical barriers to trade. In cooperation and coordination with relevant agencies, including regulatory agencies, USTR is responsible for monitoring U.S. compliance with WTO and any other international obligations relating to technical regulations, standards, and conformity assessment procedures, and for discussing with foreign governments any TBT-related "specific trade concerns" on U.S. measures that they have raised. This ongoing interaction among agencies responsible for trade and regulatory matters builds understanding of, and advocacy for, trade-facilitative regulatory practices.

18. During interagency review of U.S. trade and trade-related investment policies, advice is generally sought from private sector trade advisory committees²⁴ and from Congress.²⁵ The trade advisory committee system was established by Congress in the Trade Act of 1974, as amended. Over 800 advisors serve on these committees which USTR administers jointly with the Departments of Agriculture, Commerce, and Labor, and EPA. The trade advisory committees help the U.S. Government identify trade barriers and provide advice on key objectives and negotiating positions for multilateral, bilateral, and regional trade negotiations, as well as other trade-related policy matters. In particular, USTR and Commerce administer 16 Industry Trade Advisory Committees (ITACs), which comprise approximately 350 private-sector advisors who represent the U.S. industry sector. USTR and Commerce officials meet at least quarterly with the ITAC on Standards and Technical Trade Barriers (ITAC 16), which is composed of cleared advisors from businesses, trade associations,

²³ Ibid.

²⁴ Ibid., pp. 237-240.

²⁵ The congressional committees that have jurisdiction with respect to international trade are the House Committee on Ways and Means and the Senate Committee on Finance. Other congressional committees that USTR may consult include the House Committees on Agriculture and Energy and Commerce, and the Senate Committees on Agriculture, Commerce, and Environment and Public Works.

standards developers, and conformity assessment bodies.²⁶ USTR also meets with other ITACs and advisory committees to receive advice on TBT issues affecting specific industry sectors, such as steel, chemicals, automobiles, processed foods, and textiles, or specific regulatory areas, such as labour and environment.

V. PUBLIC CONSULTATION

19. The Administrative Procedure Act (APA) provides the foundation for regulatory transparency and accountability in the United States. The APA requires that agencies undertake a notice and comment process open to all members of the public, both foreign and domestic, for all rulemakings.²⁷ In accordance with the Act, agencies publish proposed technical regulations and conformity assessment procedures in the *Federal Register* and solicit public comment. Officials at the U.S. WTO TBT Enquiry Point review the *Federal Register* on a daily basis and notify proposed technical regulations and conformity assessment procedures to the WTO. Proposed rules currently open to public comment are also centrally located on one Federal website (www.regulations.gov). The public can use this site to send their comments electronically to agencies on proposed rulemakings published for comment in the *Federal Register*. Agencies consider the public comments, and publish the final rule in the *Federal Register*, including an announcement of when the rule will take effect, the basis and purpose of the rule, and a response to the public comments on the proposal.²⁸

20. To help the public identify planned rulemakings of international interest, beginning in fall 2008 the United States added an "international flag" to the *Unified Agenda* and *Regulatory Plan*.²⁹ These semi-annual (Agenda) and annual (Plan) publications provide uniform reporting of data on regulatory and deregulatory actions under development throughout the Federal government. The public can now search both documents for a list of entries with international impacts, and can combine such a search with other data elements of interest, such as rulemakings by a particular Federal agency, or whether or not the rule is economically significant or has small business impacts.

VI. RECOMMENDATIONS

21. This submission has outlined what the United States believes are the three critical pillars for ensuring that agencies follow good regulatory practice and that their regulations adhere to TBT Agreement obligations - strong central government management of a Member's regulatory regime, effective interagency trade policy coordination, and robust public consultation - and describes how the United States has attempted to operationalize those concepts within its regulatory system. We believe that our experience underscores the importance of institutionalizing each of these elements through laws, regulations, procedures, guidance, and other mechanisms, as well as the creation or designation of institutions within Members' governments to oversee the regulatory process.

22. The United States recommends to the Committee that Members share views and experiences on the role of domestic regulatory and trade policy coordination, as well as public consultation mechanisms, in implementing good regulatory practices and preventing the creation of unnecessary technical barriers to trade.

²⁶ See http://www.ustr.gov/Who_We_Are/List_of_USTR_Advisory_Committees.html.

²⁷ The terms "rule" and "rulemaking" are "terms of art" in the United States and refer to a broader group of measures that also encompass technical regulations and conformity assessment procedures.

²⁸ Most of the U.S. States also have an equivalent to the Administrative Procedure Act and publish proposed technical regulations and conformity assessment procedures in their individual state gazettes. The U.S. WTO TBT Inquiry Point monitors the StateNet electronic database, which compiles proposed technical regulations and conformity assessment procedures from throughout the fifty U.S. States, and notifies them to the WTO.

²⁹ See <http://www.reginfo.gov/public/do/eAgendaMain>.

23. In that context, we also recommend that Members submit to the Committee descriptions of the processes, mechanisms, and institutions they have in place to (1) ensure the technical regulations and conformity assessment procedures they adopt are consistent with international obligations; (2) address "specific trade concerns" raised by other Members bilaterally, in comments submitted through the Enquiry Points, or in the Committee itself; and (3) ensure consistency between the positions they take with respect to other Members' measures and their own measures. Sharing experiences on these issues, including how existing systems help Members take comments into account in finalizing particular measures, could assist other Members in establishing their own processes and mechanisms, as well as in making adjustments to existing systems that may be performing suboptimally.

24. The United States would also recommend that Members explore the establishment of mechanisms to coordinate trade and regulatory policy at the central government level, or to consider possible improvements to existing mechanisms and institutions, as the case may be.
